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REMARKS

Continued prosecution and consideration of the claimed subject matter in the above-identified patent application is respectfully requested.

Claims 26 through 33 are in the case and are before the Examiner. It is to be noted that claim 31 was allowed prior to the appeal and although noted in the Appeal Brief as being allowed, was not itself appealed. It is therefore believed that that claim should also be deemed to be present in the present application.

A. The Action

1. Response to Response to Arguments

The Action in response to the Remand to the Examiner by the Board asserts that each protein that is present in the mammalian brain but not in the cells of the liver, kidney, gut, lung heart or skeletal muscle (brain-specific) must also be neuroactive, and notes without citation or declaration in support that myelin is produced in the brain and not the other tissues mentioned but "does not possess a neuroactive function per se." The specification is said therefore to fail in enabling the full scope of the invention. The Action continues by asserting that the specification is lacking in enablement under the holding in *Hybritec Inc. v. Monoclonal Antibodies, Inc.* as cited in Applicant's Brief in that undue experimentation would be required. Neither of these assertions were made a part of a rejection, but will be dealt with nonetheless.

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It is first noted that the claims have been misconstrued. Thus, rather than asserting that every brain-specific proteinoid is also neuroactive, the claims relate to those cDNAs of specified length that are complementary to mRNA that encodes a neuroactive proteinoid. Thus, the phrase "said messenger RNA encoding a neuroactive proteinoid" is a test for the cDNA and its complementary mRNA. Being a test, all mRNAs that encode proteinoids that are present in the brain need not be brain-specific.

It is further submitted that myelin was a poor choice of a substance that is brain-specific in that it is produced by Schwann cells that are present in nerves throughout the body. It is submitted that the tissues other than brain recited in the claims are not unicellular, and contain nerve cells as well as other cells. Myelin will therefore be encoded by the cells of those tissues.

The Action's reliance on the *Hybritech* case is intriguing inasmuch as most of the enablement argument of the Brief is unanswered and centered around *Angstadt* and *Wands*. Applicant's Brief laid out a modified *Wands* approach to illustrate enablement, and that approach has not been refuted. There is no step needed to carry out the invention that could not be regularly practiced at the time the parental application was filed. The Examiner's attention is invited to the second full paragraph on page 9 of that Brief where the Court's comments on

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"undue experimentation" are discussed. It is submitted that nothing noted in the Action related to an alleged lack of enablement would "require ingenuity beyond that to be expected of one of ordinary skill in the art..." [*In re Angstadt and Griffen*, 190 USPQ 214, 218 (CCPA 1976)].

2. Rejection Under 35 USC § 112, Second Paragraph

The Court in *In re Moore and Janoski*, 169 USPQ 236, 238 (CCPA 1971) noted that where rejections were present under both of the first two paragraphs of Section 112, it is appropriate to deal first with the Second Paragraph rejection so that it can first be determined what subject matter the claims encompass.

The Board and the Action assert that the claims are indefinite because of their use of the term "neuroactive". This basis for rejection cannot be agreed with and is respectfully traversed.

It is first noted that the Applicant and counsel were never notified of a hearing regarding this application. This lack of notice occurred despite counsel's Request for Oral Hearing that was mailed on June 26, 1996 and was received by the Patent Office on June 28, 1996. Should the Examiner wish copies of the paper and date-stamped return post card, counsel will be pleased to provide them. Nonetheless, perhaps if counsel had been notified, he could have been there to show the board where the specification discussed neuroactivity.

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To that end, the Examiner's attention is now directed to the disclosure that begins at line 15 of page 44 and continues through line 32 of page 45, and that under Section "IV L." that begins at about line 7 of page 65 and continues through line 5 of page 66. The Examiner's attention is also invited to Section "V D" that begins on line 34 of page 74 and continues through page 79, and particularly the text that bridges pages 74 and 75 that provide illustrative examples of neuroactivity. It is thus seen that the assertion at page 5 of the Remand is incorrect. This basis for rejection should be withdrawn for that reason alone.

In addition, shortly after receiving the Remand to whose oral argument he was not invited, the undersigned caused a search to be conducted by NERAC, Inc. for the use of the term "neuroactive" prior to 1984, a time about six months after the filing of the parental application. A copy of that search is enclosed herewith as Exhibit I.

As will be seen, workers of ordinary skill in this art used the term "neuroactive" in at least 150 published papers prior to 1984. As will be seen from the highlighted word "neuroactive" (shown within a gray box) that word appeared in more than half of the titles of those 150 plus articles. Documents 198-151 of that search are U.S. Patents that are presumptively valid and free of indefiniteness. In view of the art-based recognition given to the word "neuroactive" as evidenced by the NERAC, Inc. search, the fact that a

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specification is directed to those of ordinary skill in the art [*Multiform Desiccants, Inc. v. Medzam, Ltd.*, 45 USPQ2d 1429, 1432 (CAFC 1998)], it submitted that there is no indefiniteness in the use of the word "neuroactive", and this rejection should be withdrawn.

3. Rejection Under 35 USC § 112, First Paragraph

a. Claims 26-30 and 32 and 33

Claims 26-30 were rejected as allegedly lacking enablement regarding the use of the word "neuroactive". The Action assumed the term to mean "having neurotransmitter function..." for the sake of argument. It has already been shown that those skilled in the art had a much better understanding of this term than the Board, and as such, this rejection should be withdrawn.

The Remand's comments at page 6 relating to the "circumstantial and preliminary" were true as far as they went, but the Board once again failed to read the entire text. Again had counsel been invited to attend as he asked, we might not be here now. The sentence after that quoted by the Board reads:

"Nevertheless, it is believed that the p1B236 proteinoid or one or more of its cellularly processed derivatives are neurotransmitters."

The next four paragraphs describe use of P5, P6 and P8 in studies with two types of brain cells and reported a change in the firing rate of those cells and alteration of glutamate-induced stimulation. The Examiner's attention is again invited

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to page 75, as noted above. Thus, the complete paragraph quoted plus the four paragraphs thereafter unequivocally indicate that neuroactivity for the recited peptides, and this basis for rejection should be withdrawn.

b. Claim 26

The Action asserts that "the specification does not reasonably provide enablement for the full scope of the claimed invention" in as much as no further data are provided except for the four clones: p1A75, P1B236, 1B208 and p0-40 in that claim 26 is directed to "any cDNA that is expressed exclusively in the brain". The Action indicates in a footnote that the Examiner notes that that the disclosure allegedly "fails to provide any evidence that [the above] clones ... have any neuroactive function", thereby providing an alternative basis for rejection. These bases for rejection are respectfully traversed.

It is first noted that the previous discussion has rebutted the assertion about an alleged lack of neuroactive function. The "alternative" rejection of the footnote should be withdrawn.

The Examiner's attention is invited the earlier prosecution in this application, and particularly to the discussion of documents CA, CB and CC of the IDS as well as documents DA, DB, DC, and DD that accompanied the Response filed on April 11, 1995. Those cited and supplied papers were by workers of ordinary skill in this art. It is submitted that the comments and citations to the work disclosed in this application by those workers who are of ordinary skill in this art illustrate more than ample enablement for the full scope of this invention.

The Court in *In re Angstadt and Griffen*, above, also held that the inventor need not make every species encompassed by their claims even in an unpredictable art. (At 218.) In addition, that Court held that:

"[i]f one skilled in this art wished to make and use a transition metal salt other than

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those disclosed in appellants' 40 runs, he would merely read appellants' specification for directions how to make and use the catalyst complex to oxidize the alkylaromatic hydrocarbons, and could then determine whether hydroperoxides are, in fact, formed. The process discovered by applicants is not complicated, and there is no indication that special equipment or unusual reaction conditions must be provided when practicing the invention. One skilled in this art would merely have to substitute the correct mass of a transition metal salt for the transition metal salts disclosed in appellants' 40 runs." [190 USPQ at 218.]

It is respectfully submitted that the substantially same situation is present here. Although the manipulations may be arduous and time-consuming, those manipulations are and were common-place in laboratories at the time this invention was made. As such, the papers provided previously in this prosecution illustrate that others were able to use the techniques disclosed here to make and use their own brain-specific proteinoids. Again, this basis for rejection should be withdrawn.

c. Claims 32 and 33

The Action also asserts that claims 32 and 33 are not properly enabled. The Action again asserts that each and every brain-specific mRNA must also be neuroactive. This basis for rejection is respectfully traversed.

Although it is agreed that the mRNA of the claims must encode a neuroactive proteinoid, the neuroactivity is separately assayed, as noted previously. As a result, the neuroactive proteinoid-encoding mRNAs are a subgroup of all of the brain-specific mRNAs. As already noted, the specification adequately illustrates methods for measuring neuroactivity and those skilled in the art knew how to assess such activity as can be seen from the 151 disclosures of Exhibit I. Thus, again, this rejection should be withdrawn.

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Summary

Each basis for rejection has been dealt with and has been overcome or otherwise made moot.

It is therefore believed that this application is in condition for an action on the merits and for allowance of all of the claims. An early notice to that effect is earnestly solicited.

A Petition for a three Month Extension of Time to Respond is enclosed. Please charge our Deposit Account No. 23-0920 in the amount of \$475.00 for that extension. No further fee or petition is believed to be necessary. However, should any further fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution.

Respectfully submitted,

By   
Edward P. Gamson Reg. No. 29,381

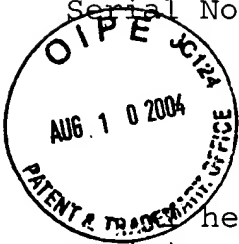
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Enclosure

Petition  
Exhibit I



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CERTIFICATE OF MAILING

hereby certify that this Reply and its enclosure, and the Petition are being deposited with the United States Postal Service as First Class mail, postage prepaid in an envelope addressed to Commissioner for Patents, Mail Stop AMENDMENT, P.O. Box 1450, Alexandria, VA 22313-1450, on August 6, 2004.

Edward P. Gamson; Reg. No. 29,381

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